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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,114	04/07/1999	SHIMON SAKAGUCHI	07898/038001	1911

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EXAMINER

SORBELLO, ELEANOR

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 04/30/2002

22

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/284,114

Applicant(s)

SAKAGUCHI, SHIMON

Examiner

Eleanor Sorbello

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 10-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-12, 14-17 and 19 is/are rejected.
- 7) ☒ Claim(s) 13 and 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/7/02 has been entered.

### *Response to amendment*

2. Applicant's amendment filed 2/7/02 paper number 21 has been entered. Claims 10, 11 have been amended, claims 1-9 have been canceled, and claims 12-19 have been added. **Claims 10-19 are pending.** Applicant's amendments and arguments have been thoroughly reviewed, but are persuasive to a point for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's argument.

3. Applicant's arguments are addressed below on a per section basis. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Claim Objections*

4. Claims 10, 11, 14 are objected to for depending from claim 12, rejected under 101, non-statutory subject matter, as stated in paragraph 5.

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5. Claim 13 is objected to because the claim recites that a mouse is deposited at ATCC. However, it is the embryo that is deposited.

Therefore, it is suggested that the claim (line 2) be amended as follows:

- - wherein the embryo - - is inserted after "and".

6. Claim 18 is objected to because it recites deposit of a mouse strain. Therefore it is suggested that the claim is amended as follows:

Claim 18 (line 2): - - from the embryo deposited as - - inserted after "strain".

***Claim Rejections - 35 USC § 101***

7. Claims 12, 14 are rejected under 35 USC § 101 as being directed to non-statutory subject matter, for reasons of record. Applicant's arguments have been fully considered but they are not persuasive.

Applicants have deposited the mouse or mouse embryo of their invention that has an ATCC accession No: FERM BP-7790, as recited in claim 13. However, claim 12 still reads on a product of nature, because a distinction from a naturally occurring BALB/C mouse has not been claimed. Any BALB/C mouse has the potential to develop rheumatoid arthritis in the future. Applicants did not stipulate any characteristic or limit the claim in any way so that one can be assured that this strain has the characteristic claimed.

***Claim Rejections - 35 USC § 112***

8. Claims 10-12, 14-17, 19 are rejected under U.S.C. 112, first paragraph, because the specification, while being enabling for a mouse strain SKG from BALB/C mouse, a method of identifying a therapy that decreases symptoms of rheumatoid arthritis, and a method of producing offspring of a mouse strain SKG, does not reasonably provide enablement for any of the above using any BALB/C mouse. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants argue that claim 12 recites the phenotypic difference (page 10, paragraph 3, of Response dated Feb. 7, 2002) between applicant's mouse strain and normal BALB/C mouse strain. However the claim recites that the mouse comprises a trait of developing natural onset rheumatoid arthritis, with no specifics as to what one of skill is to look out for. Applicant's further direct examiner to evidence in the specification ie. examples 2-5 and Figures 1-13 that show the differences between the forelegs and hind legs of a normal mouse and those of the claimed mouse. However, the claim is silent as to these limitations.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 10-12, 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Yamanaka et al.(US Pat. 4,950,741).

Yamanaka et al. teach a BALB/C mouse comprising a trait of developing rheumatoid arthritis. (col. 2, lines 22-25, col. 17, lines 66-67, col. 18, lines 1-10). Yamanaka also teaches that the presence of RF (rheumatoid factor) is one method of quantifying the degree of rheumatoid arthritis in a patient. Yamanaka also discloses a monoclonal antibody against rheumatoid arthritis.

Therefore, Yamanaka teaches all the limitations required of the claims which rejected.

### **Conclusion**

11. Claims 10-12, 14-17, 19 are rejected.

12. Claim 13, 18, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Any inquiry concerning this communication should be directed to Eleanor Sorbello, who can be reached at (703)-308-6043. The examiner can normally be reached on Mondays-Fridays from 6.30 a.m. to 3.00 p.m. EST.

Questions of formal matters can be directed to the patent analyst, Patsy Zimmerman, whose telephone number is (703) 308-0009.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

If the claims are amended canceled and/or added the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (<http://www.uspto.gov>) and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED to facilitate further examination.

  
DEBORAH J. REYNOLDS  
SUPERVISORY PATENT EXAMINER  
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